

REMARKS

This Response is submitted in response to the Office Action mailed on May 5, 2003.

Claims 8-20 are pending. The Office Action rejects Claims 8, 9, 16 and 17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In addition, Claims 8-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,317,838 ("*Cherukuri I*") in view of U.S. Patent No. 4,639,368 ("*Niazi*"). Finally, Claims 16-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Cherukuri I* in view U.S. Patent No. 4,753,805 ("*Cherukuri II*"). In response, Claims 8, 9, 16 and 17 have been amended. Applicants respectfully submit that all of the above-mentioned rejections have been overcome or are improper for reasons set forth below.

Claims 8, 9, 16 and 17 stand rejected under 35 U.S.C. § 112, second paragraph. In response, these claims have been amended to correct the informalities cited by the Examiner. These amendments have been made for clarification purposes and do not affect the scope of the claims in any manner. Applicants note for the record that they do not intend to disclaim any claimed subject matter via the amendment.

The present invention provides a product including a medicament comprising a consumable center and a coating. The coating includes a medicament and surrounds the consumable center and comprises at least 50% by weight of the product. The invention further provides a product including a medicament having a consumable tableted center and a coating. The coating includes a medicament and surrounds the tableted center and provides at least 50% of the product by weight. Applicants respectfully submit that each of the cited references fails to teach or arguably suggest a number of the features of the claimed invention.

Claims 8-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Cherukuri I* in view of *Niazi*. Applicants submit this rejection is in error.

Cherukuri I discloses a chewing gum product which includes a coating and a method of applying the same. *Cherukuri I* discloses that the coating syrup and dusting mix may be applied more than once to build up a desired coating weight and thickness. See Col. 2, lines 31-34. However, *Cherukuri I* completely fails to disclose or suggest any chewing gum compositions in which the coating comprises at least 50% by weight of the product. Indeed, the highest amount of coating disclosed in *Cherukuri I* is 35% by weight of the product. See Col. 4, lines 29-34.

As such, there is no question that *Cherukuri I* fails to teach or even arguably suggest a chewing gum composition which includes a coating that comprises at least 50% by weight of the product. As discussed above this limitation is included in each independent claim. Moreover, as admitted by the Patent Office *Cherukuri I* also fails to teach or suggest the incorporation of a medicament into a chewing gum coating. See Office Action at 3.

Niazi fails to remedy the deficiencies of *Cherukuri I* on several fronts. *Niazi* merely relates to a chewing gum composition including a medicament and taste maskers. Moreover, *Niazi* clearly states that "stick gum is generally preferred for the reason that it is less likely to be mistakenly ingested by children." See Col. 2, lines 49-51. The disclosure of *Niazi* is completely devoid of any teaching or suggestion as to a chewing-gum-composition-including-a-coating that comprises at least 50% by weight of the product. Indeed, *Niazi* does not even discuss coating the disclosed "chewing gum sticks" at all.

Accepting, *arguendo*, the Examiner's position that one skilled in the art could combine the disclosure of *Niazi* with the disclosure of *Cherukuri I*, the Examiner still has failed to present a *prima facie* case of obviousness. In this regard, the Patent Office states the expected result of combining these references would be "a composition comprising confections, and a sugarless coating which comprises a medicament that surrounds the center of a chewing gum." See Office Action at 4. However, this analysis completely ignores the fact that *Niazi* **only** teaches incorporation of a medicament into the gum base. See Col. 5, lines 51-60. Where is there any motivation or suggestion within either of these references to incorporate a medicament into a coating? Indeed, insofar as *Niazi* only teaches the incorporation of a medicament into a chewing gum base, it clearly constitutes a teaching away from the instant invention which requires the medicament be contained within the coating.

In ascertaining the appropriateness of a particular reference as the basis for a rejection under §103, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984). Accordingly, Applicants respectfully submit that this rejection has been overcome and request withdrawal of same.

Claims 16-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Cherukuri I* in view of *Cherukuri II*. Applicants submit this rejection is improper and request withdrawal of same.

Cherukuri II fails to remedy the deficiencies of *Cherukuri I*. In this regard, some of the infirmities of *Cherukuri II* include the fact there is no disclosure to use a coating and no disclosure or suggestion to place a medicament in the coating. The Patent Office's own citation to *Cherukuri II* exposes the weakness of this obviousness rejection. As set forth in the Office Action on page 5, *Cherukuri II* only teaches the incorporation of "a medicament" into the gum tablet. See Col. 9, lines 30-50. Once again, why would one skilled in the art be motivated to incorporate a medicament into a coating when combining these two references? Put another way *Cherukuri I* does not disclose any medicament at all and *Cherukuri II* only teaches that the medicament should be incorporated into the gum tablet.

Further, there is no disclosure or suggestion in *Cherukuri* that the coating comprises at least 50%-by-weight of the product. All of these above mentioned-limitations are included in the claims. Accordingly, for at least these reasons Applicants respectfully submit that this obviousness rejection has been overcome and request withdrawal of same.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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